# CENTER FOR DRUG EVALUATION AND RESEARCH

*APPLICATION NUMBER:*

**21-559**

# CORRESPONDENCE

05.14.03

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-559

**DISCIPLINE REVIEW LETTER**

Sabex 2002 Inc.
Attention: George Zorich
Agent for Sabex 2002 Inc.
c/o Roundtable Healthcare Partners
272 East Deerpath, Suite 350
Lake Forest, IL 60045

Dear Mr. Zorich:

Please refer to your August 14, 2002, new drug application (NDA) submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Infuvite Adult (multiple vitamins for infusion) Pharmacy Bulk Package.

We also refer to your submissions dated October 29 and November 15, 2002, and March 10, and April 6 and 29, 2003.

Our review of the Chemistry, Manufacturing, and Controls section of your submission is complete, and we have identified the following deficiencies:

1. **Chemistry, manufacturing and controls**: The chemistry, manufacturing and controls (CMC) information should be revised as follows:

   The acceptance specifications for *dl*-alpha-tocopheryl acetate (Vitamin E acetate) should be revised to include a test for benzo(a)pyrene content with the acceptance criteria of "NMT 1 ppb." Vitamin E acetate batches may be accepted, regarding benzo(a)pyrene content by the supplier's Certificate of Analysis. In the absence of such testing (for every received batch of vitamin E acetate), the drug product manufacturer should perform the testing. Analytical methodology may be submitted as a literature reference, or may be submitted *in toto* to the NDA. This information should be submitted to this pending application as either (1) an amendment containing the requested change or (2) a commitment to submit a "Changes Being Effected" (CBE-0) supplement within 6 months after approval.

2. **Nomenclature**: The proposed proprietary name for the drug product, INFUVITE ADULT [redacted], is not acceptable, since the term '[redacted] is not applicable to a pharmacy bulk package (PBP). Drug products, which are packaged as PBP's do not contain preservatives and cannot be entered more than one time. The term "[redacted] An alternate name should be proposed for the drug product.

3. **Labeling**: The labeling should be revised in order to comply with the requirements for Pharmacy Bulk Packages (PBP's) and to clarify the instructions for use. The revisions should include the following:

a. **Package Insert**: the following revisions should be made to the package insert.

(1) The statement "**Pharmacy Bulk Package – Not for Direct Infusion**" should be included on the first page of the package insert, positioned between the nomenclature and the DESCRIPTION section. The statement should be prominently displayed (boxed and bolded).

(2) The first paragraph of the description section should mention that the product is a pharmacy bulk package, *i.e.*, **INFUVITE ADULT [Pharmacy Bulk Package] is a sterile product consisting of 2 vials – 1 each of Vial 1 (50 mL) and Vial 2 (50 mL Fill in 100 mL Vial), provided as a pharmacy bulk package.** In addition, the term "pharmacy bulk package" should be defined in this section; the definition provided in USP General Chapter <1>, under **Definitions**, PHARMACY BULK PACKAGE may be used verbatim. This definition states "A pharmacy bulk package is a container of a sterile preparation for parenteral use that contains many single doses. The contents are intended for use in a pharmacy admixture program and are restricted to the preparation of admixtures for intravenous infusion."

(3) The time frame for dispensing the PBP contents should be included in the package insert in the DOSAGE AND ADMINISTRATION section. A maximum time frame for dispensing of 4 hours after penetrating the closure may be provided without supporting microbiological data. If a longer time frame is requested, microbiological data are needed to support such a statement; evidence must be provided that the container, once penetrated, will not support microbiological growth.

(4) The directions for dispensing from the Pharmacy Bulk Package should be presented in a continuous fashion. The instructions provided in the draft labeling provided in the amendment dated October 29, 2002. The PBP dispensing instructions should be concise, continuous, and describe the recommended procedure in chronological order, walking the practitioner through the entire process, from the choice of a suitable work environment (e.g., laminar flow hood) to the time frame for dispensing (see first comment, immediately above).

b. **Immediate Container Labels**: the following revisions should be made to the immediate container labels.

(1) The time frame for dispensing the PBP contents is stated as "withdrawal of container contents should be completed within This time frame needs to be supported by microbiological data, as mentioned in the deficiencies for the package insert above. A 4-hour time frame may be provided on the labeling without microbiological justification.

c. **Outer Label**: the following revisions should be made to the outer label.

(1) The time frame for dispensing the PBP contents is stated as "withdrawal of container contents should be completed within [redacted] This [redacted] time frame needs to be supported by microbiological data, as mentioned in the deficiencies for the package insert, above. A 4-hour time frame may be provided on the labeling without microbiological justification.

(2) [redacted]

4. **Request for commitment:**

[redacted]

We are providing these comments to you before we complete our review of the entire application to give you preliminary notice of issues that we have identified. In conformance with the prescription drug user fee reauthorization agreements, these comments do not reflect a final decision on the information reviewed and should not be construed to do so. These comments are preliminary and subject to change as we finalize our review of your application. In addition, we may identify other information that must be provided before we can approve this application. If you respond to these issues during this review cycle, depending on the timing of your response, and in conformance with the user fee reauthorization agreements, we may not be able to consider your response before we take an action on your application during this review cycle.

If you have any questions, call Enid Galliers, Chief, Project Management Staff, at (301) 827-6429.

Sincerely,

*{See appended electronic signature page}*

Mamta Gautam-Basak, Ph.D.
Chemistry Team Leader II for the
Division of Metabolic and Endocrine Drug Products, HFD-510
DNDC II, Office of New Drug Chemistry
Center for Drug Evaluation and Research

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/s/
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Mamta Gautam-Basak
5/14/03 04:33:24 PM

**Food and Drug Administration**
**Center for Drug Evaluation and Research**
**Office of Drug Evaluation ODE II**

# FACSIMILE TRANSMITTAL SHEET

**DATE: May 14, 2003**

| | |
|---|---|
| **To:** George Zorich | **From:** Enid Galliers |
| **Company:** Sabex 2002 Inc. | Division of Division of Metabolic and Endocrine Drug Products |
| **Fax number:** 847-~~589-8550~~ 482-9215 | **Fax number:** 301-443-9282 |
| **Phone number:** 847-739-3296 | **Phone number:** (301) 827-6429 |

**Subject:** Discipline Review Completed for NDA 21-559 and Information Request for Pending NDA 21-646 (2 letters)

**Total no. of pages including cover:** 8 RESPONSE TO NDA 21-559 IS NEEDED URGENTLY!!!!

**Comments:**

We are providing these comments to you before we complete our review of the entire application to give you preliminary notice of issues that we have identified. In conformance with the prescription drug user fee reauthorization agreements, these comments do not reflect a final decision on the information reviewed and should not be construed to do so. These comments are preliminary and subject to change as we finalize our review of your application. In addition, we may identify other information that must be provided before we can approve this application. If you respond to these issues during this review cycle, depending on the timing of your response, and in conformance with the user fee reauthorization agreements, we may not be able to consider your response before we take an action on your application during this review cycle.

**Document to be mailed:** ☑ YES ☐ NO



Attachment

criterion of NMT 1 ppb) and submit the revised acceptance specification for Vitamin E acetate to the Agency in an amendment to your pending applications. Alternatively, you may submit - in an amendment to your pending applications - a commitment to submit a "Changes Being Effected" (CBE-0) supplement within 6 months after approval of each NDA.

If you have any questions, call Enid Galliers, Chief, Project Management Staff, at (301) 827-6429.

Sincerely,

*{See appended electronic signature page}*

Mamta Gautam-Basak, Ph.D.
Chemistry Team Leader II for the
Division of Metabolic and Endocrine Drug Products, HFD-510
DNDC II, Office of New Drug Chemistry
Center for Drug Evaluation and Research

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/s/

Mamta Gautam-Basak
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04.06.03

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-559

# INFORMATION REQUEST LETTER

Sabex 2002 Inc.
Attention: George Zorich
Agent for Sabex 2002 Inc.
c/o Roundtable Healthcare Partners
272 East Deerpath, Suite 350
Lake Forest, IL 60045

Dear Mr. Zorich:

Please refer to your August 14, 2002 new drug application (NDA) submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Infuvite Adult — Multiple Vitamins for Infusion).

We are reviewing the Administrative section of your submission and have the following information requests. We request a prompt written response in order to continue our evaluation of your NDA.

1. Submit a Debarment Statement signed by both you as the U.S. agent and the appropriate official from Sabex.

2. Submit Patent Information and, if relevant, a Patent Certification. Again, this must be signed by you and a Sabex official.

3. As with all chemistry, manufacturing, and controls information for either an NDA or a supplement, provide a copy of that information to the appropriate FDA Field Office and submit a copy of the Field Office Certification to this application.

4. Although we have received Forms FDA 356h signed either by you or by Ms. Ferreira, please provide a new Form FDA 356h signed by both of you when you submit the other requested information. (We need to have certain forms and certifications signed by both the foreign applicant and by the U.S. agent.)

If you have any questions, call me at (301) 827-6429.

Sincerely,

*{See appended electronic signature page}*

Enid Galliers
Chief, Project Management Staff
Division of Metabolic and Endocrine Drug Products
Office of Drug Evaluation II
Center for Drug Evaluation and Research

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/s/
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Enid Galliers
4/6/03 06:05:24 PM

# facsimile
TRANSMITTAL

to: Mr. George Zorich (Phone - 847-737-3296)
fax #: 847-589-8550
re: NDA 21-559 Sabril Infantile Adult -1
date: 6 APRIL 2003
pages: 4 (including cover page)

Please provide the requested information as soon as possible



**Division of Metabolic and Endocrine Drug Products**

From the desk of...
Enid Galliers
Chief, Project Management Staff (HFD-510)
DMEDP, ODE II, CDER, FDA
5600 Fishers Lane, Rm 8B-45
Rockville, MD 20857

301-827-6429
Fax: 301-443-9282

04.06.03

# NDA REGULATORY FILING REVIEW
**(Including Memo of Filing Meeting)**

NDA # 21-559

Trade Name: Infuvite Adult
Generic Name: Multiple Vitamins for Infusion
Strengths:

Applicant: Sabex 2002 Inc.

Date of Application: August 14, 2002
Date of Receipt: August 16, 2002
Date clock started after UN: -------
Date of Filing Meeting: October 8, 2002
Filing Date: October 15, 2002
User Fee Goal Date: June 16, 2003

Indication(s) requested: No new indications. This application only adds a pharmacy bulk pack (PBP). Currently, Sabex has an approved adult parenteral multivitamin product, NDA 21-163, Infuvite Adult, which is supplied in single dose cartons comprised of two different vials, Vial 1 and Vial 2, and cartons of 10 each of Vial 1 and Vial 2.

Type of Application: Original (b)(2) NDA yes

NOTE: If the application is a 505(b)(2) application, complete the 505(b)(2) section at the end of this summary.

Therapeutic Classification: S
Resubmission after a withdrawal? n/a Resubmission after a refuse to file? n/a
Chemical Classification: (1,2,3 etc.) 5
Other (orphan, OTC, etc.) n/a

User Fee Status: no fee X (no fee b2)
Waived (e.g., small business, public health)
Exempt (orphan, government)

Form 3397 (User Fee Cover Sheet) submitted: YES
User Fee ID # N/A
Clinical data? NO, Referenced to NDA # 21-163

Is there any 5-year or 3-year exclusivity on this active moiety in either a (b)(1) or a (b)(2) application? NO

Does another drug have orphan drug exclusivity for the same indication? NO

If yes, is the drug considered to be the same drug according to the orphan drug definition of sameness [21 CFR 316.3(b)(13)]? N/A

Is the application affected by the Application Integrity Policy (AIP)? NO

If yes, has OC/DMPQ been notified of the submission? N/A

- Does the submission contain an accurate comprehensive index? YES
- Was form 356h included with an authorized signature? Two forms submitted: one with agent's signature, one with applicant's signature.

**Needs 356h signed by agent and applicant.**
**If foreign applicant, both the applicant and the U.S. agent must sign.**

- Submission complete as required under 21 CFR 314.50? YES

- If an electronic NDA, does it follow the Guidance? N/A
**If an electronic NDA, all certifications must be in paper and require a signature.**
Which parts of the application were submitted in electronic format? NONE

Additional comments:

- If in Common Technical Document format, does it follow the guidance? N/A

- Is it an electronic CTD? N/A
**If an electronic CTD, all certifications must be in paper and require a signature.**
Which parts of the application were submitted in electronic format?
Firm submitted two electronic labeling amendments: one of the package insert in MSWord format, and another with the PI as a pdf file and the labels in another pdf file. No electronic 356h or cover letter was submitted, however.

Additional comments:

- Patent information included with authorized signature? NO
**Needed**
- Exclusivity requested? NO
Note: An applicant can receive exclusivity without requesting it; therefore, requesting exclusivity is not required.

- Correctly worded Debarment Certification included with authorized signature? NO
**Needs debarment certification sent**

NOTE: Debarment Certification must have correct wording, e.g.: "I, the undersigned, hereby certify that _____ Co. did not and will not use in any capacity the services of any person debarred under section 306 of the Federal Food, Drug and Cosmetic Act in connection with the studies listed in Appendix ____." Applicant may not use wording such as "To the best of my knowledge . . . ."

- Financial Disclosure information included with authorized signature? NOT NEEDED
**(Forms 3454 and/or 3455 must be used and must be signed by the APPLICANT.)**
No covered studies submitted.
- Field Copy Certification (that it is a true copy of the CMC technical section)? NO
**Needs Field Copy Certification.**

**Refer to 21 CFR 314.101(d) for Filing Requirements**

- PDUFA and Action Goal dates correct in COMIS? YES
If not, have the document room staff correct them immediately. These are the dates EES uses for calculating inspection dates.

- Drug name/Applicant name correct in COMIS? NO
- List referenced IND numbers: N/A
- End-of-Phase 2 Meeting(s)? NO
- Pre-NDA Meeting(s)? NO

## Project Management

- Package insert consulted to DDMAC? N/A
- Trade name (plus PI and all labels and labeling) consulted to ODS/Div. of Medication Errors and Technical Support? YES
- MedGuide and/or PPI (plus PI) consulted to ODS/Div. of Surveillance, Research and Communication Support? N/A
- If a drug with abuse potential, was an Abuse Liability Assessment, including a proposal for scheduling, submitted? N/A

**If Rx-to-OTC Switch application:** N/A

- OTC label comprehension studies, all OTC labeling, and current approved PI consulted to ODS/ Div. of Surveillance, Research and Communication Support? N/A
- Has DOTCDP been notified of the OTC switch application? N/A

## Clinical

- If a controlled substance, has a consult been sent to the Controlled Substance Staff? N/A

## Chemistry

- Did applicant request categorical exclusion for environmental assessment? YES
  If no, did applicant submit a complete environmental assessment? NO
  If EA submitted, consulted to Nancy Sager (HFD-357)? N/A
- Establishment Evaluation Request (EER) submitted to DMPQ? YES
- If parenteral product, consulted to Microbiology Team (HFD-805)? YES

**If 505(b)(2) application, complete the following section:**

- Name of listed drug(s) and NDA/ANDA # 21-163, Infuvite Adult (Mutiple vitamins for Infusion)
- This new NDA 21-559 differs from the approved NDA 21-163 in adding a new Pharmacy Bulk Package (PBP) container. The contents of the PBP are the same as the package included in NDA 21-163. The size of the container and the instructions for use are the only from NDA 21-163.
- Is the application for a duplicate of a listed drug and eligible for approval under section 505(j) as an ANDA? (Normally, FDA will refuse-to-file such NDAs.) NO
- Is the extent to which the active ingredient(s) is absorbed or otherwise made available to the site of action less than that of the reference listed drug (RLD)? (See 314.54(b)(1)). If yes, the application should be refused for filing under 314.101(d)(9). NO
- Is the rate at which the product's active ingredient(s) is absorbed or otherwise made available to the site of action unintentionally less than that of the RLD? (See 314.54(b)(2)). If yes, the application should be refused for filing under 314.101(d)(9). NO
- Which of the following patent certifications does the application contain? Note that a patent certification must contain an authorized signature. **Needed. None was submitted.**
- ____ 21 CFR 314.50(i)(1)(i)(A)(1): The patent information has not been submitted to FDA.

  ____ 21 CFR 314.50(i)(1)(i)(A)(2): The patent has expired.

  ____ 21 CFR 314.50(i)(1)(i)(A)(3): The date on which the patent will expire.

  ____ 21 CFR 314.50(i)(1)(i)(A)(4): The patent is invalid, unenforceable, or will not be infringed by the manufacture, use, or sale of the drug product for which the application is submitted.

  *IF FILED, and if the applicant made a "Paragraph IV" certification [21 CFR 314.50(i)(1)(i)(A)(4)], the applicant must submit a signed certification that the patent holder was notified the NDA was filed [21 CFR 314.52(b)]. Subsequently, the applicant must submit documentation that the patent holder(s) received the notification ([21 CFR 314.52(e)].*

  ____ 21 CFR 314.50(i)(1)(ii): No relevant patents.

  ____ 21 CFR 314.50(i)(1)(iii): The patent on the listed drug is a method of use patent and the labeling for the drug product for which the applicant is seeking approval does not include any indications that are covered by the use patent. Applicant must provide a statement that the method of use patent does not claim any of the proposed indications.

  ____ 21 CFR 314.50(i)(3): Statement that applicant has a licensing agreement with the patent owner (must also submit certification under 21 CFR 314.50(i)(1)(i)(A)(4) above.)
  ____ Written statement from patent owner that it consents to an immediate effective date upon approval of the application.

- Did the applicant:
  - Identify which parts of the application rely on information the applicant does not own or to which the applicant does not have a right of reference? N/A
  - Submit a statement as to whether the listed drug(s) identified has received a period of marketing exclusivity? N/A
  - Submit a bioavailability/bioequivalence (BA/BE) study comparing the proposed product to the listed drug? N/A
  - Certify that it is seeking approval only for a new indication and not for the indications approved for the listed drug if the listed drug has patent protection for the approved indications and the applicant is requesting only the new indication (21 CFR 314.54(a)(1)(iv).? N/A
- If the (b)(2) applicant is requesting exclusivity, did the applicant submit the following information required by 21 CFR 314.50(j)(4): N/A
  - Certification that each of the investigations included meets the definition of "new clinical investigation" as set forth at 314.108(a). N/A
  - A list of all published studies or publicly available reports that are relevant to the conditions for which the applicant is seeking approval. N/A
  - EITHER
    The number of the applicant's IND under which the studies essential to approval were conducted.

    N/A

    A certification that it provided substantial support of the clinical investigation(s) essential to approval if it was not the sponsor of the IND under which those clinical studies were conducted? N/A
- Has the Director, Div. of Regulatory Policy II, HFD-007, been notified of the existence of the (b)(2) application? NO

ATTACHMENT

# MEMO OF FILING MEETING

**DATE:** October 8, 2002

**BACKGROUND:**

Infuvite Adult is already approved as an adult parenteral multivitamin product under NDA 21-163. The sponsor, Sabex 2002, submitted a supplement to NDA 21-163 dated August 14, 2002, (received on August 16. 2002) for a new container, a Pharmacy Bulk Package (PBP). However the submission was incorrectly submitted as a supplement, since the User Fee "Bundling" Policy declares that Pharmacy Bulk Packages require a separate NDA. The submission was administratively changed to a new NDA numbered NDA 21-559, and an acknowledgement letter was sent the sponsor on September 20, 2002. The sponsor claimed this application to be a non-user fee-paying 505(b)(2) NDA and the User Fee Staff concurs.

**ATTENDEES:**

Sheldon Markofsky, Ph.D., Acting Team Leader
David Lewis, Ph.D., Reviewing Chemist
Paul Stinavage, Ph.D., Reviewing Microbiologist
Hae-Young Ahn, Ph.D., Supervisory Biopharmaceutics
Jean Temeck, Medical Reviewer
Enid Galliers, Chief, Project Management Staff

**ASSIGNED REVIEWERS:**

| Discipline | Reviewer |
|---|---|
| Chemist: | David Lewis |
| Environmental Assessment (if needed): | David Lewis |
| Microbiology, sterility: | Paul Stinavage |
| Regulatory Project Manager: | Steve McCort |

Per reviewers, are all parts in English or English translation? YES

**CLINICAL** FILE __x___ REFUSE TO FILE _____

- Clinical site inspection needed: NO
- Advisory Committee Meeting needed? NO

**BIOPHARMACEUTICS** FILE __x___ REFUSE TO FILE _____

No Biopharm review needed:

**PHARMACOLOGY** FILE __x___ REFUSE TO FILE _____

- No Pharm Review needed:

**CHEMISTRY** FILE __x___

- Establishment(s) ready for inspection? YES
- Microbiology YES

***ELECTRONIC SUBMISSION***: NO

**REGULATORY CONCLUSIONS/DEFICIENCIES:**

N/A___ The application is unsuitable for filing. Explain why:

___X___ The application, on its face, appears to be well organized and indexed. The application appears to be suitable for filing.

___X___ No filing issues have been identified.

___N/A___ Filing issues to be communicated by Day 74. (Application arrived before the PDUFA 3 requirement became effective. )

List (optional): Needs the following items signed by the agent and the applicant.
356H; Debarment Certification; Field Copy Certification; Patent Certification; Patent Information.

**ACTION ITEMS:**

No action needed. The application is fileable.

January 29, 2003
Drafted by: Steve McCort
Regulatory Project Manager, HFD-510

April 6, 2003
Finalized by: Enid Galliers
CPMS, DMEDP

**This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.**

/s/

Enid Galliers
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**********
*** TX REPORT ***
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TRANSMISSION OK

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| TX/RX NO | 1425 |
| CONNECTION TEL | 918474829215 |
| CONNECTION ID | |
| ST. TIME | 06/16 13:45 |
| USAGE T | 05'57 |
| PGS. SENT | 12 |
| RESULT | OK |

Food and Drug Administration
Division of Metabolic and Endocrine
Drug Products, HFD-510
Center for Drug Evaluation and Research
Office of Drug Evaluation II

# FACSIMILE TRANSMITTAL SHEET

DATE: 6/16/03 Received fax 151

To: George Zorich From: Kati Johnson

Company: Division of Metabolic and Endocrine Drug Products

Fax number: 847-482-9215 Fax number: (301) 443-9282

Phone number: 847-739-3296 Phone number: 301-827-6380

Subject: AP letter, NDA 21-559

Total no. of pages including cover: 12

Comments:

Document to be mailed: ☒ YES ☑ NO

09.20.02

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-559

Sabex 2002 Inc.
Attention: George Zorich
U.S. Agent
c/o Roundtable Healthcare Products
272 East Deerpath Suite 350
Lake Forest, IL 60045

Dear Mr. Zorich:

We have received your new drug application (NDA) submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for the following:

Name of Drug Product: Infuvite Adult (multiple vitamins for infusion) Pharmacy Bulk Package

Review Priority Classification: Standard (S)

Date of Application: August 14, 2002

Date of Receipt: August 16, 2002

Our Reference Number: NDA 21-559

Unless we notify you within 60 days of our receipt date that the application is not sufficiently complete to permit a substantive review, this application will be filed under section 505(b) of the Act on October 15, 2002, in accordance with 21 CFR 314.101(a). If the application is filed the user fee goal date will be June 16, 2003.

Please cite the NDA number listed above at the top of the first page of any communications concerning this application. Address all communications concerning this NDA as follows:

U.S. Postal Service/Courier/Overnight Mail:

Food and Drug Administration
Center for Drug Evaluation and Research
Division of Metabolic and Endocrine Drug Products, HFD-510
Attention: Division Document Room, 8B-45
5600 Fishers Lane
Rockville, Maryland 20857

Please note that addition of a Pharmacy Bulk Package (PBP) requires submission of a separate NDA and a separate package insert. We have administratively designated your supplement to NDA 21-163 dated August 14, 2002, as a new NDA. Submit a package insert for the PBP as an amendment to this new NDA promply.

If you have any questions, call Steve McCort, Regulatory Project Manager, at (301) 827-6415.

Sincerely,

*{See appended electronic signature page*
*}*

Steve McCort
Regulatory Project Manager
Division of Metabolic and
Endocrine Dug Products, HFD-510
Office of Drug Evaluation II
Center for Drug Evaluation and Research

**This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.**

/s/
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Stephen McCort
9/20/02 04:39:22 PM